For Immediate Release

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ENZI: SENATE PASSAGE OF BIPARTISAN FDA LEGISLATION A "MONUMENTAL VICTORY FOR PATIENT SAFETY"

Washington, D.C. –U.S. Senator Mike Enzi (R-WY), Ranking Member of the Senate Health, Education, Labor and Pensions (HELP) Committee, today said the Senate has taken a bold step to protect American consumers and patients, voting to approve a comprehensive bill to enhance drug safety that provides new resources for post-market surveillance and review of new drugs and medical devices - key improvements to ensure that drugs and devices are safe and effective.

"Each day, half of all Americans take at least one prescription drug," Enzi said. "Today we have risen above partisan politics to deliver a monumental victory for all Americans who want peace of mind that the drugs they purchase to treat illnesses and chronic medical conditions are safe and effective. This bill will meet the challenges of protecting American consumers and patients and usher in a new era of drug safety."

"This bill will establish a system that gives the FDA, through sound science and remarkable innovation, the tools to get drugs to the market quickly and efficiently, especially when lives are on the line and people need new drugs and therapies," Enzi said. "It gives the FDA new authority to take swift, appropriate, and decisive action to ensure patient safety and protect consumers when new information comes to light to expose unexpected risks."

The Senate approved final passage of the "Food and Drug Administration Revitalization Act" by a 93-1 count.

The bill represents over a year of bipartisan discussions and cooperation following the Vioxx incident. It establishes a system of active surveillance for drugs already on the market, and explicitly gives the FDA new authority through Risk Evaluation and Mitigation Strategies (REMS) to respond quickly and appropriately when previously unknown risks arise.

"Right now, the FDA has its hands tied behind its back when it tries to manage the risks of drugs already on the market. This bill will clarify and strengthen the FDA's authority and give it new tools to take measured and appropriate steps to protect the health and safety of Americans when the agency's post-market surveillance signals

potential dangers from a drug or therapy. Pulling a drug from the market and denying patients who need it shouldn't be the only tool available to the FDA."

The Senate approved S. 1082 with the following amendments: Brownback #985, Inhofe # 987, Gregg #993, Landrieu #1004, Levin #1005, Murkowski #1006, Hatch #1009, Stabenow #1011, Casey # 1019, Feingold # 1026, Obama #1041, Roberts/Harkin #1047, Kennedy/Enzi #1049, Enzi #1050, Kennedy/Enzi #1053, and Reed/Isakson #1056.

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